REMARKS

Claims 11-20 are currently pending in the instant application.

Applicants request reconsideration of the objections and rejections as stated in the Office Action dated September 8, 2004, based on the following remarks.

Claim Rejections - 35 U.S.C. § 102

In the Office Action, dated September 8, 2004, the Examiner maintained the rejection of Claims 11-13 and 15-17 under 35 U.S.C. § 102(b) as being anticipated by Franz *et al.* (U.S. 4,411,882). The Examiner asserted:

> ...the broadest reasonable interpretation of the limitation "plant substance" does not exclude Ergot alkaloids because it does not limit such substances to any specific plants. Plant substances as describe[ed] in page 6, para 0021 of the specification are any substance that may be derived from plants. Ergot Alkaloids fall within the scope of the limitation, because it is isolated from a *Clavicep purpurea* that grows on rye and wheat and thus is derived from a plant. Therefore, Ergot alkaloids are within the scope of such limitation.
>
> Further, Examiner adds that the term fungus, as described by Webster's II, New Riverside University Dictionary, is describ[ed] as any of numerous plants of the division or subkingdom Thallophyta. See Webster II at p. 512. Since *Clavicep Purpurea* is a fungus within the meaning of Webster's II, it [] thus fall[s] within the kingdom of plant. Therefore, alkaloid ergots are viewed to be within the scope of the instant limitation of "plant substance."

Applicants respectfully assert that the Examiner is incorrect and request that the Examiner reconsider the rejection. First, Applicants note that the definition of "fungus" as recited in Webster II at p. 512 is ***outdated***. Fungi are no longer classified as part of the Plant Kingdom. Rather, fungi are classified as a separate kingdom as part of the "Five Kingdom Classification" created by Robert Whittaker. *See* Natural History – Phylogeny, (copy of webpage enclosed herewith and available at http://www.nearctica.com/nathist/phylog.htm, hereinafter "Natural History – Phylogeny"). As stated in Natural History – Phylogeny:

> The phylogeny of living organism has changed dramatically in the past few years. As a consequence you will find that different sites may give[] different, ***and sometimes conflicting, systematic arrangements for the same group of organisms***. Nowhere is this more true than for the "lower organisms," i.e. those groups traditionally treated as bacteria, protozoans, algae and fungi. The traditional older arrangement divided [life] into two main group[s]; the Monera (bacteria and blue-green algae) and the Eucaryotes (protozoa, algae, plants, fungi, and animals). This older scheme was [supplanted] by the so-called "Five Kingdom Classification" created by Robert Whittaker. The "Five Kingdom Classification" divided all living organisms into five kingdoms:
>
> - Kingdom Monera – Bacteria and blue-green algae
> - Kingdom Protista – Protozoa and some of the algae
> - ***Kingdom Plantae – Plants***
> - ***Kingdom Fungi – Fungi***
>   - Chytridiomycota (Chytrids)
>   - Zygomycota (Bread molds)
>   - Ascomycota (Sac and cup fungi, yeasts mildews)
>   - Basidiomycota (Club fungi, rusts and smuts)
>   - Fungi Imperfectae
>   - "Lichens"
> - Kingdom Animalia – Animals

See Natural History – Phylogeny at page 1. As indicated, *Claviceps purpurea* belongs to the fungal division "Ascomycota," which is not considered to be part of the Plant Kingdom. As such, *Claviceps purpurea* is not properly considered to be a "plant."

Further, one skilled in the art would not interpret "plant substance" to include *Claviceps purpurea*. The Plant Kingdom and Fungal Kingdom are classified separately based on distinguishing characteristics. First, all members of the Plant Kingdom are photosynthetic autotrophs, meaning that they contain chlorophyll and use light a source of

energy to synthesize carbohydrates, lipids, proteins, and other organic molecules. Fungi, in contrast, are heterotrophs, meaning that they have to absorb their nutrients from the surrounding medium by secreting food acids and hydrolytic enzymes. As such, fungi are not plants, and in fact, fungi like *Claviceps purpurea* are pathogens of plants that secrete enzymes to degrade and absorb nutrients from plants such as corn, wheat, and rye. Fungi, like *Claviceps purpurea*, decompose complex molecules in plants to simpler compounds that the fungi can absorb and assimilate. Similarly, animals such as birds, mice, and humans are heterotrophs in that animals ingest corn, wheat, and rye to digest complex molecules and obtain nutrients from simpler compounds. One skilled in the art would not consider *Claviceps purpurea* to be a "plant substance" (*i.e.*, "a substance derived from a plant") for the same reason that one skilled in the art would not consider birds, mice, and humans to be "plant substances" (*i.e.*, "substances derived from plants"). Heterotrophs ***degrade "plant substances"*** into simpler compounds (*e.g.*, by secretion, ingestion, *etc.*) and assimilate the simpler compounds. Therefore, one skilled in the art would not consider heterotrophs, such as *Claviceps purpurea*, to be "derived from a plant substance."

With regard to the limitation "neutral core," the Examiner argues that "'neutral core' should be given its broadest reasonable interpretation consistent with the specification." As such, the Examiner argues that "neutral" should be viewed to mean "free of charge" and that "core" should be viewed to mean the innermost layer. Finding as such, the Examiner contends that Franz *et al.* meet all the elements of the instant claims.

Applicants respectfully traverse the rejection and ask the Examiner to reconsider the rejection for the following reasons. First, Applicants agree that the limitation "neutral core" should be given its broadest reasonable interpretation consistent with the specification. However, Applicants emphasize that the broadest interpretation must be ***reasonable*** and ***consistent with the specification***.

The limitation "neutral" may be interpreted to be synonymous with "inert." *See* dictionary.com definitions of "neutral" and "inert," copy of webpages enclosed herewith and available at http://dictionary.reference.com/search?q=neutral (hereinafter "neutral definition") and http://dictionary.reference.com/search?q=inert (hereinafter "inert

definition"), respectively. On page six (6) of the "neutral definition" from Webster's Revised Unabridged Dictionary © 1996, 1998 *MICRA, Inc.*, "neutral" is defined as "3: having only a limited ability to react chemically, ***not active; 'inert matter'***; 'an indifferent chemical in a reaction' [***syn: inert***, indifferent]." *See* "neutral definition" at page 6 of 7 (emphasis added).

Similarly, on page three (3) of the "inert definition" from Webster's Revised Unabridged Dictionary © 1996, 1998 *MICRA, Inc.*, "inert" is defined as "having only a limited ability to react chemically; ***not active***; 'inert matter'; 'an indifferent chemical in a reaction' [***syn:*** indifferent, ***neutral***]." *See* "inert definition" at page 3 of 4 (emphasis added). As such, "neutral" is reasonably interpreted to mean "inert," especially in a chemical context. Applicants note that the instant application relates to pharmaceutical preparations and contend that Applicants' proposed interpretation of "neutral" (*i.e.*, "inert") is ***more reasonable*** and ***consistent with the specification*** than Examiner's proposed interpretation (*i.e.*, "free of charge").

Further, those skilled in the art have interpreted "neutral" to mean "inert." Applicants have enclosed herewith product information sheets for NPpharm Suglets® (hereinafter "NPpharm Suglets®") and IPSsrl Pharmaceutical Sugar Spheres (hereinafter "IPSsrl Sugar Spheres"). As indicated by NPpharm, Suglets® are "Sphere de Sucre – ***Neutral Pellets*** – Sugar Spheres – ***Neutral Core***" that "Meet all the specifications of the USP/NF, Ph. Eur., JP." NPpharm also states that "[s]ugar spheres are ***inert pellets*** composed [of] sucrose and maize starch...Suglets are ***drug-free cores*** which are coated by a suspension or a solution of ***Active ingredients*** (with a binder)." *See* NPpharm Suglets® (emphasis added). As indicated by IPSsrl, "Sugar Spheres (***Neutral pellets***) are ***inert microgranules*** based on sucrose and corn starch." *See* IPSsrl, Sugar Spheres (emphasis added). As such, those skilled in the art use "neutral pellets" and/or "neutral cores" synonymously with "inert pellets" and/or "inert microgranules."

Therefore, viewing the specification and interpreting "neutral" in the context of pharmaceutical preparations, one skilled in the art would interpret "neutral core" to mean "inert core." Franz *et al.* do not teach or suggest "neutral cores" as that term is properly interpreted in view of the specification and in the proper context of pharmaceutical

preparations (*i.e.*, as "inert cores"). As such, Applicants respectfully contend that Franz *et al.* do not anticipate the instant claims and ask the Examiner to withdraw the rejection.

Claim Rejections - 35 U.S.C. § 103

In the Office Action, the Examiner also maintained the rejection of Claims 11-20 under 35 U.S.C. § 103 as being unpatentable over Franz *et al.*. Applicant respectfully traverse the rejection. As noted above, Franz *et al.* do not disclose "a layer containing ***a plant substance***" as recited in the pending claims. Neither do Franz *et al.* disclose coating a "***neutral core***" as recited in the pending claims. Therefore, Franz *et al.* do not disclose all the limitations of the pending claims.

Further, Franz *et al.* do not suggest the limitations of the present claims. The problem intended to be solved by Franz *et al.* is the preparation of a galenic composition of ergot alkaloids, with prolonged effect, and with an improved bioavailability (col. 1, lines 7-10). Franz *et al.* attempt to solve this problem by applying an ***enteric coating*** onto an ***active core*** to prepare a prolonged release formulation (col. 1, lines 28-35). In contrast, the present invention is not a prolonged release formulation. Rather, it relates to a process for preparing a reproducible, homogenous and stable formulation, allowing a high dosage of plant extract by coating a ***neutral core*** with a layer containing a ***plant substance***. As such, one skilled in the art, in view of Franz *et al.*, would not be motivated to perform the processes recited in the pending claims. Therefore, Applicants respectfully request that the Examiner reconsider and withdraw the rejection under 35 U.S.C. § 103 over Franz *et al.*

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

Date 11/8/04

By M. Scott McBride

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Phylogeny

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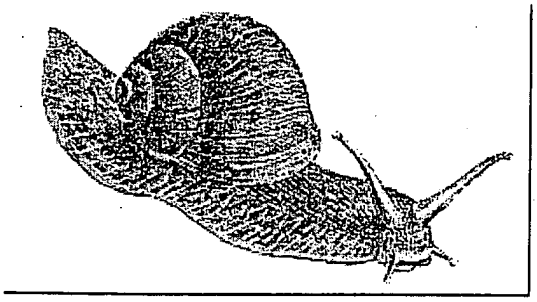

The phylogeny of living organisms has changed dramatically in the past few years. As a consequence you will find that different sites may given different, and sometimes conflicting, systematic arrangements for the same group of organisms. No where is this more true than for the "lower organisms", i.e. those groups traditionally treated as bacteria, protozoans, algae and fungi. The traditional older arrangement divided live into two main group; the Monera (bacteria and blue-green algae) and the Eucaryotes (protozoa, algae, plants, fungi, and animals). This older scheme was surplanted by the so-called "Five Kingdom Classification" created by Robert Whittaker. The "Five Kingdom Classification" divided all living organisms into five kingdoms:

Kingdom Monera - Bacteria and blue-green algae

Kingdom Protista - Protozoa and some of the algae

Kingdom Fungi - Fungi

Kingdom Plantae - Plants

Kingdom Animalia - Animals

This division of the living organisms (viruses are ignored as probably not truly living) is the scheme most generally adopted at present and you will find it in many of the sites you visit. However according to recent work there are two fundamental flaws with this system. The first flaw is relatively minor. Certain of the "bacteria" are now recognized to be fundamentally different from the rest of the Monera and probably represent the most primitive characteristics of all living organisms. These organisms have been grouped into a separate kingdom, the Archaea.

The second flaw is most serious. The major division between organisms is between those species without a defined nucleus or organelles such as mitochondria and chloroplasts (equivalent to the Monera of the Five Kingdom scheme) and those groups with a nucleus and organelles (the other four kingdoms of the Five Kingdom Scheme). This fundamental division into two groups are usually termed Procaryotes (Monera of above) and the Eucaryotes (the other four kingdoms). If one adopts this fundamental change as the definition of a kingdom, then we would be left with three kingdoms

Kingdom Archaea

Kingdom Procaryota

Kingdom Eucaryota

A simple modification of the Five Kingdom Scheme would then simply divide the Eucaryota into Protista, Fungi, Plantae, and Animalia at the next lower level. The difficultly, however, it that the group Protista does not really exist. Let me try to explain. The Protista represent a wide variety of different types of organisms representing all of the phylogenetic lines of the Eurcaryotes. Image a wide field of trees, some large, some medium size, and many small. The larger trees, the ones most visible to us, are equivalent to the plants, fungi, and animals. From the standpoint of the biologist, however, all of

the trees are equally important and distinct, not just the ones we happen to notice because the species are large and easily seen. The microscopic and the rare are equally important to the systematist. Systematists also have two rules for classifying species into groups; all of the species must have the same ancestoral species (monophyly) and if two groups are of equivalent rank (e.g. phylum, order, family, etc.) one group cannot have an ancestoral species contained in the other (i.e. no paraphyly). If these rules are followed, than all of the currently recognized major groups of the Protista, must have equivalent rank. In other words if the Animalia are treated as a kingdom, then all of the other protist groups (and there are a lot of them) must also be treated as kingdoms. The end result of this strict application of the rules, and new insights into the relationships among the groups, has led to a major upheavel in the classification of the Eucaryotes, particularly among the microscopic groups. No one can seem to agree on the correct levels to assign to each group. In addition there is still a great deal to learn about the relationships among the major groups. Therefore a certain amount of chaos now reigns and will continue to reign until the next great synthesis occurs. It also means that you can expect a certain amount of disagrement between what the various sites on the web will tell you about these relationships.

The classification given below represents an amalgamation of what we consider to be the most up to date viewpoints on the phylogeny of living organisms. However it is tentative and we do not claim it is any better or any worse than other schemes you may see elsewhere on the web. A more technical presentation may be found at the Tree of Life.

"VIRUSES"

KINGDOM ARCHAEA

KINGDOM MONERA

Eubacteria (True Bacteria)

Cyanobacteria (Blue-green Algae)

KINGDOM EUKARYOTA

THE "PROTISTS"

Parabasalia

Pelobionta (Pelomyxa)

Diplomonadida

Kinetoplastida (Bodonids and trypanosomes)

Euglenida

Apicomplexa (Apicomplexans)

Ciliata (Ciliates)

Foraminifera

Dinoflagellata (Dinoflagellates)

Radiolaria (Radiolarians)

Chlorophyta (Green algae)

Plant Divisions

Animal and Fungi Divisions

Fungi

Animals and Choanoflagellata

Chromista division (Stramenopiles)

Labyrinthulomycota (Slime nets)

Myxomycota (Slime molds)

Rhodophyta (Red algae)

Chromista Divisions

Bacillariophyta (Diatoms)

Chrysophyta (Golden algae)

Oomycota (Water molds)

Phaeophyta (Kelps and brown algae)

Prymnesiophyta (Coccolithophorids and other haptophytes)

Silicoflagellata (Silicoflagellates)

Testaceafilosea (Testate amoebae)

Xanthophyta (Yellow-green algae)

Trimerophytes

Zosterophylls

Plant Divisions (the plants)

NON-VASCULAR PLANTS

DIVISION Hepaticophyta (liverworts)

DIVISION Anthocerotophyta (hornworts)

DIVISION Bryophyta (mosses)

VASCULAR PLANTS

DIVISION Psilotophyta (whisk ferns)

DIVISION Lycophyta (club mosses)

DIVISION Sphenophyta (horsetails)

DIVISION Pterophyta (ferns)

DIVISION Pinophyta (gymnosperms)

SUBDIVISION Cycadicae (cycads)

SUBDIVISION Pinicae

Class Ginkgoatae (Ginkgo)

Class Pinatae (conifers)

SUBDIVISION Gneticae 75

Order Gnetales (Gnetum)

Order Ephedrales (Ephedra)

Order Welwitschiales (Welwitschia)

DIVISION Magnoliophyta (Angiosperms - flowering plants)

Class Magnoliopsida (dicots)

Class Liliopsida (monocots)

Fungal Divisions (the fungi)

Chytridiomycota (Chytrids)

Zygomycota (Bread molds)

Ascomycota (Sac and cup fungi, yeasts, mildews)

Basidiomycota (Club fungi, rusts and smuts)

Fungi Imperfectae

"Lichens"

Metazoan Phyla (Animals)

Porifera (Sponges)

Cnidaria (Corals, jellyfish, Hydra)

Ctenophora (Comb jellies)

Platyhelminthes (Flatworms)

Mesosoma (Mesozoans)

Nemertinea (Ribbon Worms)

Rotifera (Rotifers)

Gastrotricha (Gastrotrichs)

Kinorhyncha (Kinorhynchans)

Nematoda (Nematodes)

Nematomorpha (Hair Worms)

Acanthocephala (Acanthocephalan worms)

Entoprocta (Moss Animals)

Priapulida (Priapulids)

Sipuncula (Sipunculids)

Mollusca (Snails, clams, squid, etc.)

Echiura (Spoon worms)

Annelida (Segmented worms)

Tardigrada (Water bears)

Onychophora (Onychophorans)

Pentastomidae (Tongue Worms)

Arthropoda (Crabs, Spiders, Insects, etc.)

Cheliceramorpha (Chelicerates & kin)

Crustaceamorpha (Crustaceans)

Pycnogonida (Sea spiders)

Uniramia (Insects & kin)

- **Chilopoda (Centipedes)**
- **Diplopoda (Millipedes)**
- **Symphyla (Symphylans)**
- **Pauropoda (Pauropods)**
- **Insecta (Insects)**

Brachiopoda (Lamp shells)

Bryozoa (Moss animals)

Phoronida (Horseshoe worms)

Chaetognatha (Arrow worms)

Pogonophora (Bearded tube worms)

Echinodermata (Starfish, sea urchins, sea cucumbers, etc.)

Hemichordata (Acorn worms, graptolites)

Chordata

Urochordata (Tunicates, Sea squirts)

Cephalochordata (Lancelets)

Vertebrata (Vertebrates)

13 entries found for *neutral*.

neu·tral Pronunciation Key (n$\overline{oo}$'tr$\ni$l, ny$\overline{oo}$'-)
adj.

1. Not aligned with, supporting, or favoring either side in a war, dispute, or contest.
2. Belonging to neither side in a controversy: *on neutral ground.*
3. Belonging to neither kind; not one thing or the other.
4. Sexless; neuter.
5. *Chemistry.*
   a. Of or relating to a solution or compound that is neither acidic nor alkaline.
   b. Of or relating to a compound that does not ionize in solution.
6. *Physics.*
   a. Of or relating to a particle, an object, or a system that has neither positive nor negative electric charge.
   b. Of or relating to a particle, object, or system that has a net electric charge of zero.
7. Of or indicating a color, such as gray, black, or white, that lacks hue; achromatic.
8. *Linguistics.* Pronounced with the tongue in a middle

position, neither high nor low, as the *a* in *around.*

n.

a. A nation nonaligned with either side in a war.
b. A citizen of such a nation.

2. One who takes no side in a controversy: "I am by disposition one of life's neutrals, a human Switzerland" (John Gregory Dunne).
3. A neutral hue.
4. A position in which a set of gears is disengaged so that power cannot be transmitted.

[Middle English `neuteral`, from Old French `neutral`, from Latin `neutrālis`, *grammatically neuter*, from `neuter, neutr-`. See **neuter**.]

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neu'tral·ly *adv.*

Neu·tral [P] **Pronunciation Key** (no͞o'trəl, ny͞o'-)
n. pl. **Neutral** or **Neu·trals**

1. A confederacy of Iroquoian-speaking Native American peoples formerly inhabiting the northern shore of Lake Erie. The Neutral were destroyed by the Iroquois in the mid-17th century.
2. A member of this people.

neu·tral (no͞o'trəl, ny͞o'-)

adj.

1. Belonging to neither kind; not one thing or the other; indifferent.
2. Of or relating to a solution or compound that is neither acidic nor alkaline.
3. Of or relating to a compound that does not ionize in solution.
4. Of or relating to a particle, an object, or a system that has a net electric charge of zero.

Source: *The American Heritage® Stedman's Medical Dictionary*

neutral

1. An investment opinion that is neither bullish nor bearish. A neutral opinion for an individual stock generally indicates the stock should not be purchased or sold.
2. Of or relating to an investment position that is likely to produce the best results if the market does not exhibit a major upward or downward movement.

Source: *Wall Street Words: An A to Z Guide to Investment Terms for Today's Investor by David L. Scott.*

Main Entry: **neu·tral**
Function: *noun*
: one that is neutral; *specifically* **:** an impartial person used in alternative dispute resolution to help resolve or to determine the matters in dispute

Source: *Merriam-Webster Dictionary of Law, © 1996 Merriam-Webster, Inc.*

Main Entry: **neutral**
Function: *adjective*

: not engaged on either side; *specifically* : not aligned with a political or ideological grouping —**neu·tral·ly** *adjective* — **neu·tral·ness** *noun*

Source: *Merriam-Webster Dictionary of Law, © 1996 Merriam-Webster, Inc.*

Main Entry: **[1]neu·tral**
Pronunciation: 'n(y)ü-tr&l
Function: *noun*
: a neutral color

Source: *Merriam-Webster Medical Dictionary, © 2002 Merriam-Webster, Inc.*

Main Entry: **[2]neutral**
Function: *adjective*
1 : not decided or pronounced as to characteristics
2 a : totally lacking in saturation : ACHROMATIC **b** : not decided in color : nearly achromatic : of low saturation
3 : neither acid nor basic : neither acid nor alkaline; *specifically* : having a pH value of 7.0 <a *neutral* solution contains both hydrogen ions and hydroxide ions at the same concentration 1.00×10^{-7} —Linus Pauling>
4 : not electrically charged

Source: *Merriam-Webster Medical Dictionary, © 2002 Merriam-Webster, Inc.*

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neutral

\Neu"tral\, a. [L. neutralis, fr. neuter. See Neuter.] 1. Not engaged on either side; not taking part with or assisting either of two or more contending parties; neuter; indifferent.

The heart can not possibly remain neutral, but constantly takes part one way or the other. --Shaftesbury.

2. Neither good nor bad; of medium quality; middling; not decided or pronounced.

Some things good, and some things ill, do seem, And neutral some, in her fantastic eye. --Sir J. Davies.

3. (Biol.) Neuter. See Neuter, a., 3.

4. (Chem.) Having neither acid nor basic properties; unable to turn red litmus blue or blue litmus red; -- said of certain salts or other compounds. Contrasted with acid, and alkaline.

Neutral axis, Neutral surface (Mech.), that line or plane, in a beam under transverse pressure, at which the fibers are neither stretched nor compressed, or where the longitudinal stress is zero. See Axis.

Neutral equilibrium (Mech.), the kind of equilibrium of a body so placed that when moved slighty it neither tends to return to its former position not depart more widely from it, as a perfect sphere or cylinder on a horizontal plane.

Neutral salt (Chem.), a salt formed by the complete replacement of the hydrogen in an acid or base; in the former case by a positive or basic, in the latter by a negative or acid, element or radical.

Neutral tint, a bluish gray pigment, used in water colors, made by mixing indigo or other blue some warm color. the shades vary greatly.

Neutral vowel, the vowel element having an obscure and indefinite quality, such as is commonly taken by the vowel in many unaccented syllables. It is regarded by some as identical with the [u^] in up, and is called also the natural vowel, as unformed by art and effort. See Guide to Pronunciation, [sect] 17.

neutral

\Neu"tral\, n. A person or a nation that takes no part in a contest between others; one who is neutral.

The neutral, as far as commerce extends, becomes a party

in the war. --R. G. Harper.

Source: *Webster's Revised Unabridged Dictionary, © 1996, 1998 MICRA, Inc.*

neutral

adj 1: neither moral nor immoral; neither good nor evil, right nor wrong 2: having no personal preference; "impersonal criticism"; "a neutral observer" [syn: impersonal] 3: having only a limited ability to react chemically; not active; "inert matter"; "an indifferent chemical in a reaction" [syn: inert, indifferent] 4: not supporting or favoring either side in a war, dispute, or contest 5: having no net electric charge; not electrified [syn: electroneutral] [ant: positive, negative] 6: lacking hue; "neutral colors like back or white" 7: of no distinctive quality or characteristics or type [ant: positive, negative] 8: lacking distinguishing quality or characteristics; "a neutral personality that made no impression whatever" n : one who does not side with any party in a war or dispute

Source: *WordNet ® 2.0, © 2003 Princeton University*

neutral

neutral in InvestorWords

Source: *InvestorWords, © 2000 InvestorGuide.com, Inc.*

neutral

neutral: in CancerWEB's On-line Medical Dictionary

Source: *On-line Medical Dictionary, © 1997-98 Academic Medical Publishing & CancerWEB*

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- Thesaurus.com - Search for synonyms and antonyms

7 entries found for *inert*.

in·ert Pronunciation Key (ĭn-ûrt′)
adj.

1. Unable to move or act.
2. Sluggish in action or motion; lethargic. See Synonyms at inactive.
3. *Chemistry.* Not readily reactive with other elements; forming few or no chemical compounds.
4. Having no pharmacologic or therapeutic action.

[Latin iners, inert- : in-, *not*; see **in-**[1] + ars, *skill*; see ar- in Indo-European Roots.]

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in·ert′ly *adv.*
in·ert′ness *n.*

Source: *The American Heritage® Dictionary of the English Language, Fourth Edition*

in·ert (ĭn-ûrt')
adj.

1. Sluggish in action or motion; lethargic.
2. Not readily reactive with other chemical elements; forming few or no chemical compounds.
3. Having no pharmacologic or therapeutic action.

Source: *The American Heritage® Stedman's Medical Dictionary*
Copyright © 2002, 2001, 1995 by Houghton Mifflin Company. Published by Houghton Mifflin Company.

Main Entry: **in·ert**
Pronunciation: `in-'&rt`
Function: *adjective*
1 : lacking the power to move
2 : deficient in active properties; *especially* **:** lacking a usual or anticipated chemical or biological action <an *inert* drug>
—in·ert·ness *noun*

Source: *Merriam-Webster Medical Dictionary, © 2002 Merriam-Webster, Inc.*

inert

\In*ert"\, a. [L. iners, inertis, unskilled, idle; pref. in- + ars art: cf. F. inerte. See Art.] 1. Destitute of the power of moving itself, or of active resistance to motion; as, matter is inert.

2. Indisposed to move or act; very slow to act; sluggish; dull; inactive; indolent; lifeless.

The inert and desponding party of the court. --Macaulay.

It present becomes extravagant, then imbecile, and at length utterly inert. --I. Taylor.

3. Not having or manifesting active properties; not affecting other substances when brought in contact with them; powerless for an expected or desired effect.

Syn: Inactive; dull; passive; indolent; sluggish; slothful; lazy; lifeless; irresolute; stupid; senseless; insensible.

Usage: Inert, Inactive, Sluggish. A man may be inactive from mere want of stimulus to effort; but one who is inert has something in his constitution or his habits which operates like a weight holding him back from exertion. Sluggish is still stronger, implying some defect of temperament which directly impedes action. Inert and inactive are negative, sluggish is positive.

Even the favored isles . . . Can boast but little virtue; and, inert Through plenty, lose in morals what they gain In manners -- victims of luxurious ease. --Cowper.

Doomed to lose four months in inactive obscurity. -- Johnson.

Sluggish Idleness, the nurse of sin, Upon a slothful ass he chose to ride. --Spenser.

Source: *Webster's Revised Unabridged Dictionary, © 1996, 1998 MICRA, Inc.*

inert

adj 1: unable to move or resist motion 2: having only a limited ability to react chemically; not active; "inert matter"; "an indifferent chemical in a reaction" [syn: indifferent, neutral] 3: slow and apathetic; "she was fat and inert"; "a sluggish worker"; "a mind grown torpid in old age" [syn: sluggish, torpid]

Source: *WordNet ® 2.0, © 2003 Princeton University*

inert

inert in InvestorWords

Source: *InvestorWords, © 2000 InvestorGuide.com, Inc.*

inert

inert: in CancerWEB's On-line Medical Dictionary

Source: *On-line Medical Dictionary, © 1997-98 Academic Medical Publishing & CancerWEB*

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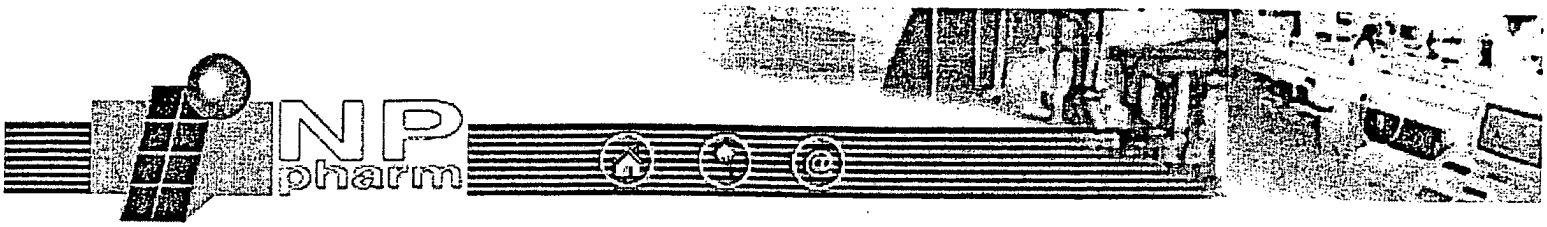

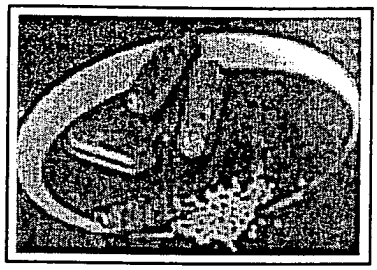

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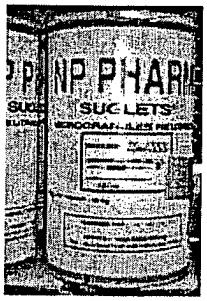
SUGLETS®

SPHERE DE SUCRE - NEUTRAL PELLETS - SUGAR SPHERES - NEUTRAL CORE

Meet all specifications of the USP/NF, Ph. Eur., JP.



Suglets are used as critical excipient for controlled or sustained release drug delivery technologies. Sugar spheres are inert pellets composed by sucrose and maize starch. Suglets offer an excellent quality : a homogeneous population of sugar spheres with a high sphericity.

Suglets are drug-free cores which are coated by a suspension or a solution of Active Ingredients (with a binder). Coating technologies used are either a classic coating process or a fluid bed coating machine.
The Suglets sphericity allows a precise calculation of the drug quantity to spray on pellets. For a drug delivery system, a second polymeric layer is applied on pellets in order to obtain the desired drug dissolution profiles.

The main advantage of using Suglets is to produce pellets with a uniformity of drug content in the final dosage form (capsules).

Suglets are available in different particle sizes (non-exhaustive list):

Size (µm) of Suglets®	Mesh
250/355	45/60
355/500	35/45
500/600	30/35
710/850	20/25
1000/1180	16/18

....	....

All intermediate sizes are available on request.

Another sizes can be realized at the specific request of users.

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PRODUCT INFORMATION

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SUGAR SPHERES (*Neutral pellets*) are inert microgranules based on sucrose and corn starch. They are intended to be used, by pharmaceutical companies, as cores in sustained and controlled release formulations in solid oral-dosage form.
IPS SUGAR SPHERES Division manufactures perfectly spherical pellets in a wide range of standard sizes, from 250 to 1700 µm.

IPS SUGAR SPHERES fully comply with the monograph "SUGAR SPHERES" of both USP/NF and European Pharmacopoeia 4th Edition, 2002 (current editions).

- PRODUCT MONOGRAPH
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- SUGAR SPHERES SUPPLY CONDITIONS
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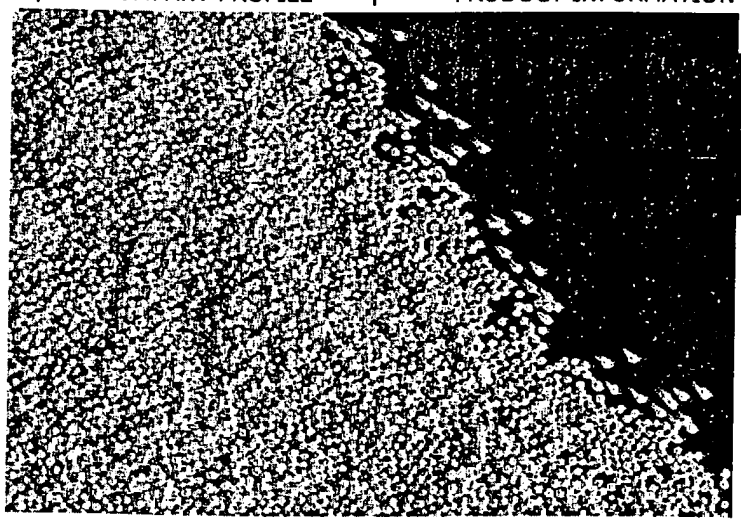
SUGAR SPHERES - The available sizes

Mesh	Size	Mesh	Size
SINGLE SIZES - standard		**DOUBLE SIZES - standard**	
# 16	(1000-1400 microns)	**# 14/16**	(1180-1400 microns)
# 18	(850-1180 microns)	**# 16/18**	(1000-1180 microns)
# 20	(710-1000 microns)	**# 18/20**	(850-1000 microns)
# 25	(600-850 microns)	**# 20/25**	(710-850 microns)
# 30	(500-710 microns)	**# 25/30**	(600-710 microns)
SINGLE SIZES - small		**DOUBLE SIZES - small**	
# 35	(425-600 microns)	**# 30/35**	(500-600 microns)
# 40	(355-500 microns)	**# 35/40**	(425-500 microns)
# 45	(250-425 microns)		
SINGLE SIZES - ultra small		**DOUBLE SIZES - ultra small**	
# 50	(250-355 microns)	**# 40/45**	(355-425 microns)
# 60	(212-300 microns)	**# 45/50**	(300-355 microns)
		# 50/60	(250-300 microns)

To visualize size specifications click on each mesh value #



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